May 11, 2004

Dr. Ralph Parod
Toxicology Department
BASF Corporation
1609 Biddle Avenue
Wyandotte, MI 48192

Dear Dr. Parod:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Quadrol posted on the ChemRTK HPV Challenge Program Web site on January 8, 2004. I commend BASF Corporation for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that BASF Corporation advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-*S*-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
M. E. Weber

**EPA Comments on Chemical RTK HPV Challenge Submission:**
**Quadrol**

## Summary of EPA Comments

The sponsor, ARCADIS G&M, Inc. submitted a test plan and robust summaries to EPA for Quadrol (*N,N,N',N*'-tetrakis(2-hydroxypropyl)ethylenediamine, CAS No. 102-60-3) and the proposed analog triisopropanolamine, CAS No. 122-20-3, dated December 8, 2003. EPA posted the submission on the ChemRTK HPV Challenge Web site on January 8, 2004.

EPA has reviewed this submission and has reached the following conclusions:

1. Analog Justification. EPA agrees that triisopropanolamine (CAS No. 122-20-3) is an acceptable analog for health and ecological effects of Quadrol. However, EPA does not agree that triisopropanolamine is a suitable analog for the biodegradation endpoint.

2. Physicochemical Properties. The submitter needs to provide a measured melting point and indicate whether the boiling point provided is measured or calculated. If calculated, a measured boiling point is needed.

3. Environmental Fate. The submitter needs to provide measured biodegradation data for Quadrol.

4. Health Effects. The data submitted for these endpoints are adequate for the purposes of the HPV Challenge Program.

5. Ecological Effects. EPA reserves judgement on the adequacy of data submitted for Quadrol for the fish study, and for the analog triisopropanolamine for the fish, daphnia, and algae studies, pending the receipt of missing study details.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

## EPA Comments on the Quadrol Challenge Submission

### Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

The data provided by the submitter for boiling point, vapor pressure, partition coefficient, and water solubility are adequate for the purposes of the HPV Challenge Program.

*Melting point.* The submitter provided a melting point value of < 25 °C for Quadrol. Open range values are generally inadequate for the purposes of the HPV Challenge Program, except those below 0 °C. The submitter needs to provide measured melting point data for Quadrol following OECD guidelines.

*Boiling point.* The submitter needs to indicate whether the boiling point value provided is measured or calculated. If calculated, the submitter needs to provide measured boiling point data following OECD guidelines.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

The data provided by the submitter for photodegradation and fugacity are adequate for the purposes of the HPV Challenge Program.

*Stability in water*. EPA agrees with the submitter in that Quadrol is expected to be stable to hydrolysis; however, the submitter needs to incorporate this information in a separate robust summary addressing 'stability in water.'

*Biodegradation.* The submitter provided estimated biodegradation data (using BIOWIN) for Quadrol and information from an inherent biodegradation study for the proposed analog triisopropanolamine. As triisopropanolamine differs substantially from Quadrol, it is not considered adequate for biodegradation data extrapolation purposes. Furthermore, an inherent biodegradation study does not adequately address the SIDS endpoint. The submitter needs to provide measured ready biodegradation data for Quadrol following OECD TG 301.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

For the purposes of the HPV Challenge program the information provided for these endpoints is adequate.

Ecological Effects (fish, invertebrates, and algae)

The submitted fish study for Quadrol, and the fish, daphnia, and algal studies for triisopropanolamine cannot be fully evaluated without more study details. EPA reserves judgement on the Quadrol and triisopropanolamine data until the submitter provides the missing study details to allow for an independent assessment of study adequacy.

## Specific Comments on Robust Summaries

Ecological Effects

For the ECOSAR predictions of the 48-hour $EC_{50}$ for daphnids and the 96-hour $EC_{50}$ for algae for Quadrol, the input parameters used in the models should be included in the robust summaries.

*Fish*. Information missing from the robust summary of the study of Quadrol in *Pimephales promelas* includes test substance purity, test temperature, dissolved oxygen concentration, and statistical methods used.

Information missing from the robust summary of the study of triisopropanolamine in *Leuciscus idus* includes mortality and effects at each concentration, fish specifications (age, mean weight, mean length, number), and statistical methods used.

*Invertebrates*. Information missing from the robust summary of the study of triisopropanolamine in *Daphnia magna* includes the number and age of daphnids used, concentrations tested, use of a control and the response observed, effects (percentage immobilization) at each concentration tested, test substance's purity, temperature, pH, dissolved oxygen concentration, and statistical methods used.

*Algae*. Information missing from the robust summary of the study of triisopropanolamine in green algae includes water quality characteristics (pH and test temperature), light intensity and quality, details about cell density and inhibition of cell growth at all concentrations tested, use of a control and the response observed, and statistical methods used.

## Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.